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510 (k) Summary

Device Name:
Normed Titanium Rondo Fix Fusion Plate and Screw System

Device Identification:
Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Class II

Product Code:
87 HRS (21 CFR – 888.3030)

Normed Titanium Rondo Fix Fusion Plate and Screw System consists of a series of convex/concave plates in various shape and length which are attached to the bone using screw fixation. The plates are available in 1.0 mm plate thickness and can be contoured as needed to fit the specific anatomy. The self-tapping 2.3 mm screw diameters will be available in two screw head designs, standard cross-lock and square lock.

Normed Titanium Rondo Fix Fusion Plate and Screw System intended for wrist arthrodesis, providing fixation of small bones such as the radius and carpal bones, patients suffering pain and/or loss of function due to osteoarthritis, post traumatic arthritis, fractures, revision of failed wrist fusions, segmental bone loss, rheumatoid arthritis and tumor resection. The system can be used in both adult and pediatric patients.

Official Contact Person:
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 2002

Albert Enayati
President
Osteomedics, Inc.
809 Carter Lane
Paramus, New Jersey 07652

Re: K022323
Trade/Device Name: Normed Titanium Rondo Fix Fusion Plate and Screw System
Regulation Number: 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: July 15, 2002
Received: July 17, 2002

Dear Mr. Enayati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for use

510 (k) Number (if known): K022323

Device Name: Normed Titanium Rondo Fix Fusion Plate and Screw System

Indications for use:

Normed Titanium Rondo Fix Fusion Plate and Screw System intended for wrist arthrodesis, providing fixation of small bones such as the radius and carpal bones, patients suffering pain and/or loss of function due to osteoarthritis, post traumatic arthritis, fractures, revision of failed wrist fusions, segmental bone loss, rheumatoid arthritis and tumor resection. The system can be used in both adult and pediatric patients.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription use Y OR OVER – THE – COUNTER USE_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022323

(Optional Format 1-2-96)